K113844

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U.S. Food and Drug Administration
Center for Devices and Radiological Health
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Date December 19th, 2011

Traditional 510(k) Summary (in accordance with 21 CFR 807.92)

1. Date of Summary
December 19th, 2011

2. Company
EIZO NANAO CORPORATION
153 Shimokashiwano, Hakusan
Ishikawa 924-8566 Japan

3. Authorized Contact Person
Hiroaki Hashimoto

4. Device Information
- Trade Name/Model: RadiForce RX240
- Common Name: 2MP Color LCD Monitor
- Classification Name: System, Image Processing, Radiological
- Classification Number: 21 CFR 892.2050, Product Code LLZ

5. Predicate Device
- Color LCD Monitor, RadiForce RS210 (K092613)

6. Device Description
The RadiForce RX240 is a color LCD monitor for viewing medical images other than those of mammography. The matrix size (or resolution) of the panel is 1200 x 1600 pixels (2MP) with a pixel pitch of 0.270 mm.

Since factory calibrated display modes, each of which is characterized by a specific tone curve (including DICOM GSDF), a specific luminance range and a specific color temperature, are stored in lookup tables within the monitor, the tone curve is e.g. DICOM compliant regardless of the display controller used.

RadiCS is application software to be installed in each workstation offering worry-free quality control of the diagnostic monitors including RX240 based on several QC guidelines. The RadiCS and its subset, RadiCS LE are included in this 510(k) submission as an accessory to the RadiForce RX240.

7. Intended Use

The RadiForce RX240 is intended to be used in displaying and viewing digital images for diagnosis of X-ray or MRI, etc. by trained medical practitioners. The device does not support the display of mammography images for diagnosis.

8. Technological Characteristics

The RadiForce RX240 can be said to have at least the same display performances as those of the predicate device by default due to the following reasons:

a. The matrix sizes (1200 x 1600) and the active area sizes (324.0 mm x 432.0 mm) of the LCD panels used by the both devices are the same.

b. The DICOM calibrated luminance (400 cd/m^2) and the typical maximum luminance (760 cd/m^2) is higher than that of the predicate device (150 cd/m^2, 300 cd/m^2). The higher luminance to be maintained constantly was realized by the employment of LED backlight deteriorating more slowly than conventional CCFL backlights.

c. The LED backlight was newly employed instead of CCFL backlight because it is mercury-free, consumes less power and deteriorates more slowly. We have not recognized any adverse effects of the LED backlight on the quality of displayed images. Refer to section 18 "Performance Testing - Bench" where several image quality characteristics of the proposed device are compared with those of the predicate device.

d. The both devices display images in accordance with DICOM GSDF by default utilizing the factory calibrated display mode stored in lookup tables inside of them.

e. Analog video interface is not supported by the proposed device. The quality of displayed images is usually better via digital interfaces like DVI or DisplayPort than via analog ones.

As for the maintenance, the same QC software is used for the both devices and the implementation of the Backlight Sensor (BS) stabilizing the backlight is also the same.

As for built-in sensors, in addition to BS common to the both devices, RX240 has three kinds of sensors. However, only the Built-in Front Sensor (IFS) has something to do with the maintenance or the calibration; the Presence Sensor (PS) detects the absence of the user to trigger the power saving mode of the monitor and the Ambient Light Sensor (ALS) is used to measure the ambient light by lx. The IFS enables automatic grayscale calibration by measuring the luminance at the screen surface. Without IFS, the grayscale calibration process requires human intervention and the use of an external sensor. The accuracy data of the calibration with

external sensors and that with the IFS is included in section 16.9 "Verification and Validation Documentation".

The overall design of the RadiForce RX240 was validated in accordance with internationally recognized safety and EMC standards by independent testing facilities and in-house ones. Besides, EIZO NANAO CORPORATION performed a range of system and performance tests to ensure that the RadiForce RX240 performs in accordance with its specifications. None of the tests revealed behaviors inconsistent with the expected performance.

9. Conclusion

The 2MP Color LCD Monitor, RadiForce RX240 is substantially equivalent to the predicate device with respect to technical characteristics, application and intended use. The specifications of the primary component employed by the proposed device are the same as those of the predicate device and other differences have been independently validated. Any differences between the devices do not affect safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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Mr. Hiroaki Hashimoto
Manager
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924-8566 HAKUSAN ISHIKAWA
JAPAN

FEB 2 7 2012

Re: K113844
Trade/Device Name: 2MP Color LCD Monitor, RadiForce RX240
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: December 26, 2011
Received: December 28, 2011

Dear Mr. Hashimoto:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K113844

Device Name: 2MP Color LCD Monitor, RadiForce RX240

Indications for Use:

The RadiForce RX240 is intended to be used in displaying and viewing digital images for diagnosis of X-ray or MRI, etc. by trained medical practitioners. The device does not support the display of mammography images for diagnosis.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S Patel

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K113844